

REMARKS/ARGUMENTS

Reconsideration is respectfully requested. Claims 1-46 were previously pending in the application. Claims 4-13, 15, 19-21, 25-31, and 36-46 have been cancelled without prejudice to filing these claims or similar claims in one or more divisional or continuation applications. Claims 1, 14, 22, and 32 have been amended. New claims 47-51 have been added. Support for amendments to claims 1 and 14 are found *inter alia* in the specification on page 2, paragraph 7 to page 3, paragraph 19. Support for amendments to claims 22 and 32 are found *inter alia* in the specification on page 9, paragraph 39. Support for new claims 47, 49, and 52 are found *inter alia* in the specification on page 17, paragraph 66. Support for new claim 48 is found *inter alia* in the specification on page 2, paragraph 7 to page 3, paragraph 19. Support for new claim 51 is found *inter alia* in the claims 1 and 14 as currently amended. Thus, no new matter has been added. Amendment and cancellation of claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Accordingly, claims 1-3, 14, 16-18, 22-24, 32-35, and 47-51 are now pending.

Restriction Requirement

Applicants acknowledge the Examiner's decision to make the Restriction Requirement final. Applicants had previously elected with traverse Group I, claims 1-4, 14-18, 22-24, 28, and 32-35. Accordingly, Applicants have cancelled claims 5-13, 19-21, 25-27, 29-31, and 36-46 by this amendment. Applicants expressly reserve the right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application or an application claiming priority from this application.

Claim rejections under 35 U.S.C. § 102(a) and (b) based on the Del Val reference

The examiner has rejected claims 1-4, 14-18, and 22-24 under 35 U.S.C. § 102(a) or (b) as allegedly being anticipated by Del Val et al. (reference 6 on the IDS submitted 2/3/03). Applicants respectfully traverse the rejection of these claims under the different sections of 35 U.S.C. § 102 as discussed below.

Rejections under 35 U.S.C. § 102(b):

In order for a publication to anticipate under 35 U.S.C. 102(b), the publication must have been accessible to the public more than one year prior to the filing of a patent application. See MPEP 2128. Applicants respectfully submit that the Del Val et al. reference was not publicly available more than one year prior to the February 4, 2002 filing date of the instant application. As the Examiner has pointed out in the Office Action, "it is customary at scientific meetings for abstract books to be available prior to the meeting or at the very least on the first day of the meeting." As evidence of the date of accessibility of the cited reference, Applicants enclose copies of pages from the journal in which the reference appeared. These pages indicate that the first day of the meeting was March 16, 2001 and that the Lane Medical Library at Stanford University received this journal on February 23, 2001. Both these dates, which indicate date of public accessibility, are less than one year prior to the Applicant's February 4, 2002 filing date. Thus, the Del Val reference does not qualify as 102(b) prior art to anticipate any of the claims of the instant application.

Rejections under 35 U.S.C. 102(a):

In order for a printed publication to anticipate under 35 U.S.C. § 102(a), the publication must describe the work of *another* before the Applicant's invention. See 35 U.S.C. 102(a). In particular, "[a]n Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. § 102(a)". MPEP 2132.01. Accordingly, Applicants enclose the declaration of Dr. Bob Buchanan, the senior author of the Del Val reference and an inventor of the instant application. Dr. Buchanan declares that a co-author of the Del Val reference, Joshua H. Wong, who was not named as an inventor in the instant application, was a post-doc working under the supervision and direction of Dr. Buchanan. Dr. Buchanan further declares that Joshua H. Wong did not make any independent contribution to the work described in the Del Val reference. Thus, the Del Val reference describes the inventive work of only the inventors listed in the instant application. For this reason, the Del Val reference does not qualify as prior art under 102(a) to anticipate any of the claims of the instant application because it

does not disclose the work of *another*. Accordingly, Applicants respectfully request that this ground for rejection be withdrawn.

Claim rejections under 35 U.S.C. § 102(b) based on U.S. Patent No. 5,736,149

The Examiner has rejected claims 14 and 16-17 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,736,149. The Examiner alleges that “[t]he ‘149 patent teaches an isolated pollen allergen that is about 30 kDa as determined by SDS-PAGE, contains cysteine residues, thereby meeting the limitation of sulfhydryl groups, and possesses allergen activity.” Office Action at page 3, paragraph 7. Based on the similarity of these physical characteristics, the Examiner alleges that the disclosure of the ‘149 patent anticipates claim 14 (and dependent claims 16-17) of the instant application. The rejection is avoided by amendment of the claims. The ‘149 patent discloses “*Sor h I*, a major allergen found in *Johnson* grass pollen.” (Emphasis added.) See the ‘149 patent *inter alia* at column 2, line 66 – column 3, line 1. In contrast, claim 14 (and, through their dependency, claims 16-17), as amended, recite, in part, “[a]n isolated *ragweed* pollen protein...” (Emphasis added.) Ragweed pollen allergen is not taught by the ‘149 patent. Because the ‘149 patent does not teach each and every element of claim 14 as amended, it can not anticipate this claim or any claims that depend from it as required under 35 U.S.C. § 102(b). For this reason, Applicants respectfully request that this ground for rejection be withdrawn.

Claim rejections under 35 U.S.C. § 102(b) based on U.S. Patent No. 5,500,347

The Examiner has rejected claims 1-4 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,500,347. In formulating this rejection, the Examiner states that SEQ ID NO. 21 (derived from CK20, a mammalian cytokeratin) of the ‘347 patent is 100% identical to SEQ ID NO: 9 of the instant invention, and he alleges that “[s]ince the claims read upon proteins and compositions of proteins comprising SEQ ID NO: 9, the claimed invention is anticipated”. See Office Action at page 4, end of paragraph 8 from previous page. However, claim 1, as amended, recites, in part, “[a]n isolated *ragweed* protein or peptide fragment thereof ... selected from the group consisting of SEQ ID NO:1 ... and SEQ ID NO:11.” (Emphasis added.) Applicants respectfully note that the protein disclosed in the ‘347 patent is an approximately 46 kDa

mammalian cytokeratin, a protein that is totally distinct and unrelated to the subject matter claimed in the instant application. The '347 patent does not teach any ragweed proteins, and in particular, the '347 application does not teach the 30 kDa ragweed protein of the instant application or the ragweed protein of claim 1. Thus, the '347 patent does not teach each and every element of claim 1 as amended. For these reasons, the 102(b) rejection of claims 1-4 is not appropriate, and Applicants respectfully request that this ground for rejection be withdrawn.

Claim rejections under 35 U.S.C. § 103(a)

As a preliminary matter, Applicants thank the Examiner for advising, in paragraph 9 of the Office Action, the Applicants of their obligation under 37 C.F.R. § 1.56 to point out any instances of lack of common ownership with respect to co-pending applications in order for the Examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. 102(e), (f), or (g) prior art under 35 U.S.C. § 103(a). Applicants wish to state that all co-pending applications are commonly owned.

The Examiner has rejected claims 32-35 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,500,347 in view of U.S. Patent No. 4,281,061. In making this rejection, the Examiner alleges that "the claimed invention differs from the prior art teachings [namely, the '347 patent] only by the recitation of putting said components in a kit with instructions." Office Action at page 4, paragraph 10. The Examiner then alleges that this limitation, missing from the '347 patent, is supplied by the '061 patent which teaches that reagents for an immunoassay can be provided as kits. Applicants respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations.

Claim 32 has been amended to recite, in part, “[a] kit for detecting *Ambt7* pollen allergen comprising one or more *ragweed* proteins . . .” (Emphasis added.) The specification of the instant application in paragraph 0060 on page 14 indicates that “*Ambt7*” is synonymous with “the 30 kDa ragweed protein allergen.” In contrast, the ‘347 patent teaches an approximately 46 kDa mammalian cytokeratin, a protein that is totally distinct and unrelated to the subject matter of claim 32. In particular, the ‘347 patent does not teach any proteins from ragweed, and in particular, the ‘347 application does not teach the 30 kDa ragweed protein or *Ambt7* of the instant application. As discussed above with reference to the anticipation rejection, the mere fact that CK20 has six amino acids that match SEQ ID NO: 9 of the instant application is solely by chance and is not relevant to the subject matter of the present invention. Thus, the ‘347 patent does not teach each and every element of claim 32 as amended. These claim elements are not supplied by the ‘061 patent which only discloses immunoassay kits. Thus, neither the ‘347 patent alone or in combination with the ‘061 patent teach each and every element or limitation of claim 32 (and its dependent claims) as required to establish a *prima facie* case of obviousness. For this reason alone, the *prima facie* case of obviousness put forth by the Examiner is rebutted, and Applicants respectfully request that this ground for rejection be withdrawn.

Claim rejections under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-4, 14, 16-17, 22-24, 28, and 32-35 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that “[t]he scope of claims 1 or 22 or 28 or 32 reads upon *any* protein or polypeptide that comprises SEQ ID NOs 1-11”. (Emphasis added.) Office Action at page 5, paragraph listed as 5. The Examiner then goes on to allege that “[t]he scope of claim 14 reads upon any 30 kDa polypeptide isolated from any source of pollen extracts”. *Id.* The Examiner further alleges that there is no description of what “additional amino acids would be in a polymorphic variant comprising SEQ IDs 1-11”, and that no other 30 kDa protein except that isolated from ragweed is disclosed in the instant application. *Id.* For these reasons, the Examiner alleges that there is inadequate “written description of a genus of thousands or even possibly

millions of proteins or polypeptides encompassed by the claims”. Applicant respectfully traverses this rejection as explained below for each group of rejected claims.

With respect to the rejection of claim 1, this claim has been amended to recite “[a]n isolated *ragweed* protein or peptide fragment thereof comprising an amino acid sequence wherein said amino acid sequence is selected from the group consisting of SEQ ID NO:1 . . . , and SEQ ID NO.11.” Applicants respectfully submit that the scope of claim 1, as amended, is not unduly broad and does not read upon *any* protein or polypeptide that comprises any of the listed sequences. Rather, the scope of the claim covers “an isolated *ragweed* protein” that comprises any of the listed sequences. The Examiner has acknowledged that “no other 30 kDa protein except that isolated from ragweed is disclosed in the instant application”. As to the claimed protein, Applicants respectfully submit that the specification provides ample written description of “an isolated ragweed protein”. For instance, the specification provides structural and chemical information on the claimed ragweed protein. In paragraph 175 of the specification, the isolated ragweed protein is described as being a 30 kDa glycoprotein which has at least one disulfide bond and a pI of about 8.0. Furthermore, it is disclosed in paragraphs 184-195 of the specification that the ragweed protein as isolated by the methods disclosed in the application yields peptides corresponding to the sequences of SEQ ID NO:1-11 when subjected to tryptic digestion. The sequence information, combined with the physical characteristics of the protein, provides structural information which uniquely describes the claimed ragweed protein.

For a similar reason, Applicants traverse the Examiner’s rejection of claims 22 and 32 on the grounds of alleged lack of written description. Amended claim 22 recites, in part, “a fragment of a *ragweed* pollen allergen *Ambt7* . . .” (Emphasis added.) Amended claim 32 recites, in part, “a kit for detecting *Ambt7* pollen allergen comprising one or more *ragweed* proteins . . .” (Emphasis added.) Applicants respectfully submit that these claims are not unduly broad in scope. Both claims cover “*Ambt7*” from *ragweed*. As disclosed in the specification in paragraph 60 on page 14, “*Ambt7*” is synonymous with “the 30 kDa ragweed protein allergen”. As discussed above, Applicants respectfully submit that the structure of the 30 kDa ragweed protein allergen, and thus *Ambt7* as well, is adequately described *inter alia* in paragraphs 175 and 184-195 of the

specification. Also, as discussed above, the Examiner has admitted that the present application discloses 30 kDa protein from ragweed. The sequence information, combined with the physical characteristics of Ambt7, provides unique structural information which uniquely describes the claimed ragweed protein of claim 32.

Furthermore, claim 14 has been amended to recite, in part, “[a]n isolated *ragweed* pollen protein...” This amendment renders moot the Examiner’s rejection of claim 14 on the alleged grounds that “[t]he scope of claim 14 reads upon *any* 30 kDa polypeptide isolated from *any* source of pollen extracts.” (Emphasis added.) Rather, claim 14 as amended reads upon a 30 kDa polypeptide isolated from *ragweed* pollen extracts, and not, from an infinite number of sources of pollen extracts. Further, as discussed above, the specification describes the structural and sequence characteristics of the 30 kDa polypeptide isolated from ragweed, further defining the scope of this claim and providing adequate written description.

Applicants note that claim 28 has been cancelled thus rendering the Examiner’s rejection of this claim moot.

For the foregoing reasons, Applicants have overcome the Examiner’s written description rejections. Applicants thus respectfully request that these grounds for rejection be withdrawn.

Claim rejections based on double patenting

The Examiner has provisionally rejected claims 2-4 and 22-24 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-3 and 8-12 of co-pending Application No. 10/067,484. The Examiner has also provisionally rejected claims 1-2, 14-18, and 32-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 8-12 of copending Application No. 10/067,620.

Applicants respectfully request that the examiner hold this provisional rejection in abeyance until such time as there is an indication of otherwise allowable subject matter for this and the

copending application. Only at that time will the applicants be able to determine whether an obviousness-type double patenting rejection is applicable.

Acknowledgment of IDS consideration

Finally, Applicants acknowledge the Examiner's consideration of reference 3 on the IDS submitted on 2/3/03 and reference 2 on the IDS submitted 7/12/04 and the fact that these references are not appropriate for publishing on the first page of a U.S. patent.


CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 416272000200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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